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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/412,268

10/05/1999

BEHNAZ PARHAMI-SEREN

MGH-1526

9455

21005

7590

05/26/2006

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EXAMINER

UNGAR, SUSAN NMN

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 05/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/412,268

Applicant(s)

PARHAMI-SEREN ET AL.

Examiner

Susan Ungar

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 16 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 7-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-6, 38-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

1. The Amendment filed March 16, 2006 in response to the Office Action of September 12, 2005 is acknowledged and has been entered. Previously pending claim 39 has been amended. Claims 1-6, 38-60 are currently being examined.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The following rejections are being maintained:

***Claim Rejections - 35 USC 112***

4. Claims 2, 5, 6, 41-43, 45-48, 49-55, 57-59 remain rejected under 35 USC 112 for the reasons previously set forth in the Action mailed September 12, 2005, Section 9, pages 6-7.

Applicant argues that submission of the Deposit Declaration concurrent with the instant response obviates the rejection. The argument has been considered but has not been found persuasive because the Deposit Declaration is still defective. The requirements for Deposit of Biological Materials were clearly set forth in the Paper mailed April 9, 2002. Applicant has still not satisfied the requirements as the instantly submitted Declaration does not make reference to the irrevocable removal of all restrictions imposed by the depositor on the availability to the public of deposited materials upon the granting of a patent. Once again, for Applicant's convenience, Examiner reiterates the requirements for a Deposit Declaration.

If a deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposits will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when

deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

Applicant's provision of these assurances would finally obviate this rejection.

5. Claims 1, 3-4 and 38 remain rejected under 35 USC 112, first paragraph and newly amended claim 39 is rejected under 35 USC 112, first paragraph, for the reasons previously set forth in the Action mailed September 12, 2005, Section 10, pages 7-8.

Applicant argues that (a) to satisfy the written description requirement a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention, (b) court has stated that the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims, (c) possession may be shown by a description in the specification of an actual reduction to practice of the claimed method, MPEP2163 (d) for a genus, the written description requirement may be satisfied through sufficient description of a representative number of species by actual reduction to practice, MPEP 2163. The argument has been considered but has not been found persuasive as (a-d) it appears that Applicant has misinterpreted the instant rejection under 35 USC 112, first paragraph. The instant rejection does not raise the written description issue of whether or not Applicant had possession of the claimed invention at the time the application was filed, rather the instant rejection raises the written description issue of whether or not the instantly claimed broad limitations had clear support in the

specification and the claims as originally filed. Applicant has attempted to broaden the scope of the invention as originally disclosed in the specification by using the specific examples of antibodies 7-1, 1-10, whose binding to Oua-BGG could not be inhibited with concentrations as high as 100 micromolar of free digoxin, to support the newly claimed limitation drawn to claim an entire subgenus. However, MPEP 2105 specifically states-in-part that “the written description requirement prevents an applicant from claiming subject matter that was not adequately described in the specification as filed. New or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement. See, e.g., *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic disclosure and specific example within the subgenus range)”. Clearly, the specific examples do not support the broadly claimed subgenus.

Further, MPEP 1504.04 specifically states-in-part that “New matter is subject matter which has no antecedent basis in the original specification, drawings or claim (MPEP § 608.04). .....An amendment to the claim which has no antecedent basis in the specification and/or drawings as originally filed introduces new matter because that subject matter is not described in the application as originally filed.” In particular, for the reasons of record, antecedent basis for the broadly claimed limitations, is not found in the claims, specification or drawings as originally filed. The argument has been considered but has not been found persuasive and the rejection is maintained.

Applicant argues that the specification teaches a monoclonal antibody or antigen binding fragment thereof having binding specificity for ouabain, wherein the antibody or antigen binding fragment does not crossreact with digoxin and

therefore claims 1, 3, 4 and 38 are not broader than original claim 1. The argument has been considered but has not been found persuasive since Applicant is not addressing the issue raised, that is that the material rejected is drawn to a concentration of digoxin as high as 100 micromolar in the absence of limitations drawn to antibody 7-1, 1-10.

Applicant argues that Applicant's have shown possession of the claimed invention. The argument has been considered but for the reasons set forth above, the argument is not relevant to the instant rejection since the instant rejection does not raise the written description issue of whether or not Applicant had possession of the claimed invention at the time the application was filed, rather the instant rejection raises the written description issue of whether or not the instantly claimed broad limitations had clear support in the specification and the claims as originally filed.

The arguments have been considered but have not been found persuasive and the rejection is maintained.

6. Claims 40-44 remain rejected under 35 USC 112, first paragraph, for the reasons previously set forth in the Action mailed September 12, 2005, Section 11, page 8.

Applicant argues that there is no *in haec verba* requirement for new or added claim language and such language can be supported in the specification through express, implicit or inherent disclosure and points to the x axis of Figure 3 that clearly indicates a monoclonal antibody or antigen binding fragment thereof which has binding specificity for ouabain and for the ouabain component of a ouabain-carrier complex wherein binding of the antibody or antigen binding fragment of ouabain is not inhibited by a concentration of digoxin as high as 25 uM. The

argument has been considered but Examiner fails to see any of express, implicit or inherent disclosure of the instantly broadly claimed limitations in the x axis of Figure 3. Figure 3 does not provide support for express, implicit or inherent disclosure of the instantly claimed limitations.

Applicant is confused by Examiner's interpretation of Figure 3 and requests clarification of Examiner's interpretation of Figure 3, wherein Examiner interpreted the Figure to show that antibodies 5A12, 7-1, 1010 to ouabain-BGG are inhibited by approximately  $10^{-5}$  digoxin. To clarify, Examiner's interpretation of the Figure is based on visual analysis. In turn, Examiner is confused by Applicant's interpretation of Figure 3 wherein it does not appear to Examiner that Figure 3 supports the broadly claimed limitations instantly rejected.

Applicant argues that Applicants have clearly shown possession of the claimed invention. The argument has been considered but has not been found persuasive for the reasons, drawn to possession, set forth above.

7. Claims 56-60 remain rejected under 35 USC 112, first paragraph, for the reasons previously set forth in the Action mailed September 12, 2005, Section 12, pages 8-9.

Applicant argues that Applicants have clearly shown possession of the claimed invention. The argument has been considered but has not been found persuasive because it appears that Applicant has again misinterpreted the instant rejection under 35 USC 112, first paragraph. The instant rejection does not raise the written description issue of whether or not Applicant had possession of the claimed invention at the time the application was filed, rather the instant rejection raises the written description issue of whether or not the instantly claimed broad limitations had clear support in the specification and the claims as originally filed.

As drawn in particular to the arguments drawn to “possession” the arguments have not been found persuasive for the reasons set forth above.

The arguments have been considered but have not been found persuasive and the rejection is maintained.

8. Claim 39 remains rejected under 35 USC 112, first paragraph for the reasons previously set forth in the Action mailed September 12, 2005, Section 13, pages 9-13.

Applicant argues that Applicant's have shown possession of the claimed invention by reducing the invention to practice. The argument has been considered but has not been found persuasive because (1) Applicant has described only a single antibody that functions as claimed and thus has not provided a representative number of antibodies (2) Applicant has not described structural features common to the members of the genus which features constitute a substantial portion of the genus or disclosed sufficiently detailed, relevant identifying characteristics, functional characteristics coupled with a known or disclosed correlation between function and structure. Reduction to practice with a single antibody does not, in the absence of (1) and (2), satisfy the written description requirement.

Applicant argues that claim 39 has been amended to indicate that binding of the antibody to ouabain is not inhibited by a concentration of digoxin, as high as 100  $\mu$ m has obviated the rejection. The argument has been considered but has not been found persuasive because the amendment does not remedy the fact that the specification as originally filed describes only a single antibody that functions as claimed, does not describe structural features common to the members of the genus which features constitute a substantial portion of the genus or disclose sufficiently



detailed, relevant identifying characteristics, functional characteristics coupled with a known or disclosed correlation between function and structure.

The arguments have been considered but have not been found persuasive and the rejection is maintained.

8. Claims 38, 44 and 60 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in the Action mailed September 12, 2005, Section 14, pages 13-17.

Applicant requests that Examiner provide support for the implicit definition of the term ‘pharmaceutical’ and appears to argue that the phrase pharmaceutical composition is not conventionally drawn to *in vivo* use of the composition for treatment. The apparent argument has been considered but has not been found persuasive given the conventional use of the phrase for *in vivo* treatment, wherein anyone of ordinary skill in the art would believe it more likely than not that a pharmaceutical composition is drawn to a medical composition for use *in vivo* for treatment. Further, and only in answer to Applicant’s request it is noted that the free online dictionary at <http://www.thefreedictionary.com/pharmaceutical> specifically teaches that the noun “pharmaceutical” refers to a drug or medicine that is prepared or dispensed in pharmacies and used in medical treatment. In any case the issue remains the same, that is, implicit in the recitation of a “pharmaceutical” composition is the *in vivo* use thereof for treatment.

Applicant points to the definition of a pharmaceutical, in Stedman’s Medical Dictionary, 26<sup>th</sup> edition wherein a pharmaceutical refers to the practice of preparing and dispensing drugs and states that a pharmaceutical is suitable for administration *in vivo* such as administration to an animal. Applicant’s discussion has been considered but is found confusing and inconsistent. It is not clear how a

pharmaceutical can refer to the practice of preparing and dispensing drugs and at the same time be suitable for administration *in vivo*. Further, it appears that Applicant's definition of a pharmaceutical is not drawn to a pharmaceutical composition but rather is drawn to the adjective definition of pharmaceutical which is, again only in answer to Applicant's arguments, conventionally understood to mean "of or relating to pharmacy or pharmacists" (see <http://www.thefreedictionary.com/pharmaceutical>) wherein it is understood that pharmacy/pharmacists prepare and dispense drugs.

Applicant argues that administration of a pharmaceutical to an animal does not necessarily have to be for treatment purposes but can also be administered to study and verify, for example, a role for ouabain as Applicants teach in the specification. The argument has been considered but has not been found persuasive because Applicant is arguing limitations not recited in the claims as currently constituted, the pharmaceutical composition is not limited to study of animal models to determine a role for ouabain and the claims as currently constituted read on the *in vivo* use of the pharmaceutical composition for treatment.

The arguments have been considered but has not been found persuasive and the rejection is maintained.

9. All other objections and rejections set forth in the previous Office Action are hereby withdrawn.
10. No claims allowed.
11. Thus, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

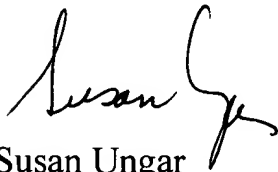
A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS

FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at 571-272-0787. The fax phone number for this Art Unit is (571) 273-8300.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.



Susan Ungar  
Primary Patent Examiner  
May 17, 2006